Amendments to the Claims

This listing of claims will replace all prior versions, and listings of claims in the application.

1. (Currently amended) A method of producing a sterile formulation comprising:

(a) mixing

(i) a cationic surfactant;

(ii) a polyoxyethylene (POE) and polyoxypropylene (POP) block copolymer; and

(iii) a polynucleotide;

at a temperature below the cloud point of said block copolymer to form a mixture; and

(b) cold filtering the mixture to produce a sterile formulation; wherein said mixing step does not require vortexing.

2. (Currently amended) The method of claim 1, further comprising:

(c) raising the temperature of the mixture above the cloud point of said block copolymer prior to ~~step (b)~~ cold filtering the mixture.

3. (Currently amended) The method of claim 1, further comprising:

(c) raising the temperature of the mixture above the cloud point of said block copolymer after ~~step (b)~~ cold filtering the mixture.

4. (Currently amended) The method of claim 1, further comprising:

(c) raising the temperature of the mixture above the cloud point of said block copolymer prior to ~~step (b)~~ cold filtering the mixture;

(d) lowering the temperature to below the cloud point of said block copolymer; and

(e) repeating ~~steps (c) and (d)~~ the sequence of raising and lowering the temperature of said mixture about 1 to about 50 times prior to ~~step (b)~~ said cold filtering the mixture.

5. (Currently amended) The method of claim 1, further comprising:

(c) raising the temperature of the mixture above the cloud point of said block copolymer after ~~step (b)~~ cold filtering the mixture;

(d) lowering the temperature to below the cloud point of said block copolymer; and

(e) repeating ~~steps (c) and (d)~~ the sequence of raising and lowering the temperature of said mixture about 1 to about 50 times.

6. (Previously presented) The method of claim 1, further comprising aliquoting said formulation into a suitable container.

7. (Previously presented) The method of claim 1, wherein said block copolymer is of the general formula:

$HO(C_2H_4O)_x(C_3H_6O)_y(C_2H_4O)_xH$; wherein (y) represents a number such that the molecular weight of the hydrophobic POP portion (C_3H_6O) is up to approximately 20,000 daltons and wherein (x) represents a number such that the percentage of the hydrophilic POE portion (C_2H_4O) is between approximately 1% and 50% by weight.

8. (Previously presented) The method of claim 7, wherein said block copolymer is the poloxamer CRL-1005.

9. (Previously presented) The method of claim 1, wherein said block copolymer is of the general formula: $HO(C_3H_6O)_y(C_2H_4O)_x(C_3H_6O)_yH$ wherein (y) represents a number such that the molecular weight of the hydrophobic POP portion (C_3H_6O) is up to approximately 20,000 daltons and wherein (x) represents a number such that the percentage of hydrophilic POE portion (C_2H_4O) is between approximately 1% and 50% by weight.

10. (Previously presented) The method of claim 1, wherein the cationic surfactant is selected from the group consisting of benzalkonium chloride, benethonium chloride, cetrimide, cetylpyridinium chloride, acetyl triethylammonium chloride, Bn-DHxRIE, DHxRIE-OAc, DHxRIE-OBz and Pr-DOctRIE-OAc.

11. (Currently amended) The method of claim 1, wherein ~~step (a)~~ said mixing is performed at a temperature of about -2°C to about 8°C.

12. (Currently amended) The method of claim 2, wherein ~~said step (c)~~ raising the temperature of the mixture above the cloud point of said block copolymer is performed at a temperature of about 8°C to about 35°C.

13. (Currently amended) The method of claim 3, wherein ~~said step (c)~~ raising the temperature of the mixture above the cloud point of said block copolymer is performed at a temperature of about 8°C to about 35°C.

14. (Currently amended) The method of claim 4, wherein ~~said step (c)~~ raising the temperature of the mixture above the cloud point of said block copolymer is performed at a temperature of about 8°C to about 35°C.

15. (Currently amended) The method of claim 5, wherein ~~said step (c)~~ raising the temperature of the mixture above the cloud point of said block copolymer is performed at a temperature of about 8°C to about 35°C.

16. (Currently amended) The method of claim 4, wherein ~~said step (d)~~ lowering the temperature of the mixture below the cloud point of said block copolymer is performed at a temperature of about -2°C to about 8°C.

17. (Currently amended) The method of claim 5, wherein ~~said step (d)~~ lowering the temperature of the mixture below the cloud point of said block copolymer is performed at a temperature of about -2°C to about 8°C.

18. (Original) The method of claim 1, wherein said cold filtering is performed at a temperature of about -2°C to about 8°C.

19. (Previously presented) The method of claim 1, wherein said cold filtering is performed using a filter with a pore size of about 0.01 microns to about 2 microns.

20. (Previously presented) The method of claim 1, wherein the final concentration of said cationic surfactant present in said formulation is from about 0.01mM to about 5mM.

21. (Previously presented) The method of claim 1, wherein the final concentration of said block copolymer present in said formulation is from about 1 mg/mL to about 50 mg/mL.

22. (Previously presented) The method of claim 1, wherein the final concentration of said polynucleotide present in said formulation is from about 1 ng/mL to about 10 mg/mL.

23. (Original) A cationic lipid selected from the group consisting of: Bn-DHxRIE, DHxRIE-OAc, DHxRIE-OBz and Pr-DOctRIE-OAc.

24. (Original) The cationic lipid of claim 23, wherein said lipid is Bn-DHxRIE.

25. (Original) The cationic lipid of claim 23, wherein said lipid is DHxRIE-OAc.

26. (Original) The cationic lipid of claim 23, wherein said lipid is DHxRIE-OBz.

27. (Original) The cationic lipid of claim 23, wherein said lipid is Pr-DOctRIE-OAc.